UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

CARETOLIVE,
a not-for-profit corp.,
Plaintiff,

v.

U.S. FOOD AND DRUG ADMINISTRATION,
Defendant.

Case No. 2:08-cv-005
JUDGE GREGORY L. FROST
Magistrate Judge Norah McCann King

OPINION AND ORDER

This matter is before the Court on Defendant's Motion to Stay (Doc. # 10), Plaintiff's Memorandum in Opposition (Doc. # 18), and Defendant's Reply (Doc. # 19). For the reasons that follow, the Court **CONDITIONALLY GRANTS** Defendant's Motion to Stay.

I. FACTUAL BACKGROUND

CareToLive ("Plaintiff") is an association of cancer patients, patient families, doctors, investors, and advocates which has requested information from the United States Food and Drug Administration ("Defendant" or "the FDA") pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 *et seq*. On September 11, 2007, the FDA's Division of Freedom of Information ("DFOI") received a FOIA request from Plaintiff dated August 15, 2007. Declaration of Frederick J. Sadler[1] ("Sadler Decl.") ¶ 10. The request sought the following:

> A copy of all letters written to the FDA (or prepared by the FDA) and purported to be from Dr. Scher, Dr. Hussain and Doctor (*sic*) Fleming in between March 29th 2007 and April 30th of 2007, regarding the [Biologics License Application] submitted for Provenge also known as Sipuleucel-T including the envelope or

[1]Mr. Sadler's Declaration, dated February 13, 2008, is attached to Defendant's Motion to Stay as Exhibit A. Mr. Sadler is the Director of DFOI, Office of Management Programs, United States FDA, located in Rockville, Maryland. Sadler Decl. ¶ 1.

> other means of communication whereby the FDA received such letters and a copy of any record of those letters then being disclosed to any media or other persons or specifically a publication called "The Cancer Letter," including the means of communication to the Cancer Letter of the Scher, Hussain and Fleming letters from the FDA or its employees to outside persons, publications or companies.

Sadler Decl., Ex. 1 at 1.

The FOIA request was the 8,316th FOIA request the FDA received in 2007. *Id.* ¶ 10. DFOI advised Plaintiff by letter dated the same day that the FOIA request had been received. *Id.* ¶ 11, Ex. 2.

DFOI initially forwarded the request to the Center for Biologics Evaluation and Research ("CBER") because the FOIA request sought records relating to an unapproved biological product regulated by that Center and to the Office of the Commissioner ("OC"), Office of the Executive Secretariat because the FOIA request sought records relating to agency correspondence. CBER responded with documents on November 6, 2007. Complaint ¶ 4; Sadler Decl. ¶ 12. OC's Office of the Executive Secretariat responded to the request through DFOI on January 24, 2008, stating that it had not located any responsive records. Sadler Decl. ¶ 13, Ex. 3.

DFOI also transmitted the FOIA request to the Division of Information Disclosure Policy ("DIDP") in the FDA's Center for Drug Evaluation and Research ("CDER"). *Id.* ¶ 14. DFOI did so because, after consultation with CBER, it appeared that CDER might also have records responsive to the request. *Id.*

DIDP received Plaintiff's FOIA request on October 15, 2007. Declaration of Nancy B. Sager[2] ("Sager Decl.") ¶ 28. DIDP assigned it to the "Complex Track" because DIDP

[2]Ms. Sager's Declaration, dated February 13, 2008, is attached to Defendant's Motion to Stay as Exhibit B. Ms. Sager is the Director of DIDP at CDER, United States Food and Drug Administration in Rockville, Maryland. Sager Decl. ¶ 1.

determined that Plaintiff's request sought documents not readily available and would require DIDP to search for and possibly redact documents. *Id.* ¶ 29. By way of explanation, once at DIDP, FOIA requests that can be answered quickly with readily available documents, and which do not require any searching or redaction, are considered "simple" and generally are processed on a faster track (known as the "Simple Track"), as opposed to "complex" requests that follow a slower processing track (known as the "Complex Track"). *Id.* ¶ 8. Requests assigned to the Simple Track do not require DIDP personnel to search for or redact documents, generally because DIDP has previously reviewed and redacted the responsive documents (*e.g.*, because they were responsive to a prior FOIA request), the requested documents are publicly available, or it is clear from the face of the request that CDER has no responsive documents. *Id.* ¶ 9. DIDP then either makes copies of previously processed documents and provides them to the requester, directs the requester to documents publicly available, or notifies the requester that CDER has no responsive documents. *Id.* ¶ 10.

DIDP attempted to contact Plaintiff's counsel on December 4, 2007, leaving a telephone message stating that DIDP follows a first-in/first-out, two track process for responding to FOIA requests, and that Plaintiff's FOIA request would be processed accordingly. *Id.* ¶ 29. DIDP left this message again on December 31, 2007. *Id.*

II. STANDARD

FOIA affords the public access to virtually any federal government record that FOIA itself does not specifically exempt from disclosure. 5 U.S.C. § 552; *Rugiero v. United States Dep't of Justice*, 257 F.3d 534, 544 (6th Cir. 2001). When an agency does not respond to a FOIA request in accordance with the time period specified by statute, the requester may seek

judicial review "to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld." 5 U.S.C. § 552(a)(4)(B). Also, in certain circumstances FOIA provides for expedited processing of requests. *See* 5 U.S.C. § 552 (a)(6)(E)(i) (expedition if compelling need shown). The district courts review agency decisions, including those regarding expedited processing of FOIA requests, *de novo*. *See id.*

III. ANALYSIS

In its motion to stay, the FDA claims that it needs a 20 month[3] stay so that it may have enough time to properly respond to Plaintiff's FOIA request. In Plaintiff's Memorandum in Opposition, Plaintiff argues that Defendant is not entitled to a stay in the normal course of responding to the FOIA request and that even if it were so entitled the stay should still be denied because Plaintiff is entitled to expedited processing of the FOIA request. The Court will address each of the parties' arguments below.

The Court, however, notes initially that, to support its position, the FDA has provided the detailed declarations of the agency's senior FOIA officials, Frederick Sadler and Nancy Sager, which are entitled to a presumption of good faith. *Rugiero*, 257 F.3d at 544. "When considering a request for an *Open America* stay, 'agency affidavits are accorded a presumption of good faith, which cannot be rebutted by purely speculative claims about the existence and discoverability of other documents.' " *Wilderness Soc'y v. United States Dep't of the Interior*, No. 04-0650, 2005 U.S. Dist. LEXIS 20042, at *21 (D. D.C. 2005) (citing *SafeCard Servs., Inc. v. Sec. & Exch. Comm'n*, 926 F.2d 1197, 1200 (D.C. Cir. 1991) (citations and internal quotation marks omitted). Courts, aware of the difficulty of wading into the internal processes and functions of agencies,

[3]Defendant's Motion to Stay was filed on February 18, 2008. Consequently, Defendant requests that this case be stayed until October 18, 2009.

recognize that such declarations "provide a critical insight into" the adequacy of an agency's processes and progress in addressing FOIA requests "and are often determinative." *Elec. Privacy Info. Ctr. v. United States Dep't of Justice*, 2005 U.S. Dist LEXIS 18876, at *11 (D. D.C. Aug. 31, 2005) (citing *SafeCard Services*, 926 F.2d at 1200).

Contrarily, Plaintiff has provided nothing but speculation and innuendo about the FDA's failure to timely respond to its requests. Thus, Plaintiff has utterly failed to rebut the presumption of good faith to which the FDA's sworn declarations are entitled.

A. The FDA's Request for a Stay

Pursuant to FOIA, an agency that has received a request for records must respond to that request within 20 working days of the date of receipt of the request. 5 U.S.C. § 552(a)(6)(A). "To prevent this deadline from becoming rigid and unworkable, however, Congress inserted a special 'safety valve.' " *Appleton v. Food & Drug Admin.*, 254 F. Supp.2d 6, 8 (D. D.C. 2003) ("*Appleton I*") (citation omitted). Specifically, Congress provided that "[i]f the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records." 5 U.S.C. § 552(a)(6)(C)(i). Thus, a party may request a stay of a case so as to provide the additional time needed to review the records. Based on the seminal case on the issue, *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605 (D.C. Cir. 1976), this type of stay is referred to as an "*Open America* stay." *See e.g., Elec. Frontier Found. v. Dep't of Justice*, 517 F. Supp.2d 111, 113 (D. D.C. 2007).

In the instant action, the FDA contends that it has shown that exceptional circumstances exist and that it is exercising due diligence in responding to Plaintiff's request. This Court

agrees.

1. Exceptional Circumstances

In *Open America*, the United States District Court for the District of Columbia explained that the "exceptional circumstances" referred to in 5 U.S.C. § 552(a)(6)(C)(i) exist when an agency "is deluged with a volume of requests for information vastly in excess of that anticipated by Congress [and] when the existing resources are inadequate to deal with the volume of such requests within the [20 day] time limit of subsection (6)(A)[.]" *Id.* at 616.

In the Electronic Freedom of Information Act Amendments of 1996[4] ("EFOIA"), Congress limited the meaning of "exceptional circumstances" to exclude "a delay that results from a predictable agency workload of requests under this section, unless the agency demonstrates reasonable progress in reducing its backlog of pending requests." *Ctr. for Pub. Integrity v. United States Dep't of State*, No. 05-2313, 2006 U.S. Dist. LEXIS 22281, at *6 (D. D.C. April 24, 2006) (citing 5 U.S.C. § 552(a)(6)(C)(ii)). "It also has been recognized, based on the legislative history, that other circumstances in addition to FOIA request backlogs may be a basis for finding exceptional circumstances, including 'resources being devoted to . . . the number of requests for records by courts or administrative tribunals.' " *Id.* at *6-7 (citing *Wilderness Soc'y*, 2005 U.S. Dist. LEXIS 20042, at *21which cited H.R. Rep. No. 104-795, at 24 (1996), reprinted in 1996 U.S.C.C.A.N. 3448, 3467). The Court will address each factor that it considered to determine that exceptional circumstances exist in this case.

a. The FDA is deluged with a volume of requests for information vastly in excess of that anticipated by Congress.

[4]EFOIA Amend. of 1996, Pub. L. No. 104-231; § 7(c), 110 Stat. 3048 (codified as amended at 5 U.S.C. § 552(a)(6)(C)(ii)).

Defendant establishes that DIDP's FOIA request workload is vastly in excess of that anticipated by Congress. Sadler Decl. ¶ 5; Sager Decl. ¶¶ 17-19. The FDA's declarations show the high volume of FOIA requests received by the FDA in general and, more specifically, by DIDP. Sadler Decl. ¶ 5; Sager Decl. ¶¶ 17-19. The FDA further shows that the raw numbers of annual FOIA requests fail to reflect their size or complexity. Because CDER is the agency component responsible for the regulation of most human drugs and therapeutic biological products, many records kept within CDER include information that is exempt from disclosure as trade secret information, confidential commercial information, personal privacy information, and/or deliberative process information. Sager Decl. ¶ 19. Careful pre-disclosure review of these records is therefore critical, legally required, and extremely time-consuming. *Id.* ¶ 18. Further, many FOIA requests are actually multiple, separate queries for documents. *Id.*

Plaintiff fails in any way to respond to Defendant's showing of a FOIA request workload that is vastly in excess of Congress' anticipation. Thus, Plaintiff has failed to overcome the presumption of good faith to which the FDA's affidavits are entitled. *Rugiero*, 257 F.3d at 544.

b. The FDA's resources are inadequate to deal with the volume of requests for information within the time limits of subsection (6)(A) of FOIA.

DIDP has struggled to increase its resources by expanding its full-time staff from 18 to 28 employees during the last five years. Sager Decl. 27(c). Even assuming immediate proficiency for each new employee whom DIDP hired from 2003-2007, the average monthly volume of DIDP's FOIA requests would require each staff member fully to complete the processing of between three and four FOIA requests per week simply to maintain pace. The complexity of many FOIA requests, intervening and superceding requests for information (due to

litigation or Congressional inquiry), and DIDP's obligation to reduce its backlog of FOIA requests, render DIDP's resources grossly inadequate to meet FOIA's 20-day production schedule for new requests.

In its opposition memorandum, Plaintiff argues that, in general, courts "should not take into account the resources of the defendant . . . ." (Doc. # 18 at 10.) However, in FOIA cases, courts routinely recognize that other circumstances, including lack of resources, should be considered. *See Ctr. for Pub. Integrity*, No. 05-2313, 2006 U.S. Dist. LEXIS 22281, at *6-7 (citing 5 U.S.C. § 552(a)(6)(C)(ii), *Wilderness Soc'y*, 2005 U.S. Dist. LEXIS 20042, at *21 which cited H.R. Rep. No. 104-795, at 24 (1996), reprinted in 1996 U.S.C.C.A.N. 3448, 3467)).

Thus, the Court shall consider the FDA's resources. *See id.* Also, the Court relies on the FDA's submitted affidavits to conclude that it has shown that its resources are inadequate to deal with the volume of requests it receives. Plaintiff has again failed to overcome the presumption of good faith to which the FDA's affidavits are entitled. *Rugiero*, 257 F.3d at 544.

c. The FDA has made reasonable progress in reducing its backlog of pending requests.

In 1996, EFOIA further elucidated the standard for obtaining an *Open America* stay of proceedings, clarifying the "exceptional circumstances" analysis to exclude any "delay that results from a predictable agency workload of requests . . . unless the agency demonstrates reasonable progress in reducing its backlog" of pending requests. 5 U.S.C. § 552(a)(6)(C)(ii). To establish reasonable progress, courts generally have considered a range of factors, including requests for additional funding, modernizing practices and equipment, and initiatives tied directly to backlog reduction. *See Elec. Frontier Found.*, 517 F. Supp.2d at 119-20 (providing specific detail of backlog reduction efforts, including reductions in processing time); *Ctr. for*

Pub. Integrity, 2006 U.S. Dist. LEXIS 22281, at *3 (describing backlog reduction initiatives, including a backlog reduction task force).

In the case *sub judice*, the FDA has shown that it has received FOIA requests at the rate of approximately 346 per month (from 2003 through 2007). DIDP's current backlog of FOIA requests is approximately 3,420. Sager Decl. ¶ 26. To reduce the backlog, DIDP has implemented new information technology systems, increased personnel resources, and is employing strategies to reduce the volume of incoming FOIA requests. DIDP's activities are described in detail in Ms. Sager's Declaration.

DIDP's efforts have yielded positive results, successfully reducing its backlog from an August 2003 high of 6,783, to approximately 3,420 requests as of January 31, 2008 – a reduction of approximately 50% in about five years. *Id. See also Ctr. for Pub. Integrity*, 2006 U.S. Dist. LEXIS 22281, at *16-17 (court determined reasonable progress made based on five-year period). Other courts have found the FDA's history of reductions in its FOIA backlog and its addition of personnel and resources to satisfy the "reasonable progress" requirement. *Appleton I*, 254 F. Supp.2d at 10-11 (finding FDA demonstrated reasonable progress in reducing FOIA backlog during 1998-2001 and that year-to-year reductions need not be uniform); *Bower v. FDA*, 2004 U.S. Dist. LEXIS 18369, at *7-8 (D. Me. Aug. 30, 2004) (accepting FDA's efforts to reduce its backlog).

Notwithstanding the FDA's declaration supporting its contention that it has made reasonable progress in reducing its backlog of pending requests, Plaintiff fails to address this issue. Consequently the Court accepts that the FDA has made reasonable progress in reducing its backlog of pending FOIA requests. *See Elec. Privacy Info. Ctr.*, 2005 U.S. Dist. LEXIS

18876, at *11 (agency declarations such as these "provide a critical insight into" the adequacy of an agency's processes and progress in addressing FOIA requests "and are often determinative").

d. The FDA must devote resources to other important tasks.

The legislative history of EFOIA indicates that other circumstances in addition to FOIA request backlogs may be a basis for finding exceptional circumstances. H.R. Rep. No. 104-795, at 24. Here, Defendant argues that DIDP's backlog is attributable to several factors other than responding to the pending FOIA requests. Indeed, Defendant persuades this Court that it must devote its scarce resources delegated to responding to FOIA requests to other important tasks such as (i) requests by courts or administrative tribunals, (ii) congressional requests, and (iii) compliance with specific legislative enactments.

(i) Requests from courts or administrative tribunals.

The FDA sets forth evidence that it is currently subject to "unusually heavy litigation demands." Sager Decl. ¶ 21. During 2007, DIDP collected, reviewed, redacted, and indexed tens of thousands of pages of documents related to multiple FOIA lawsuits, third-party subpoenas, and discovery requests in cases in which the FDA is a party. *Id.* DIDP assigned five full-time employees solely to those matters, which include several federal court cases and two multi-district litigation cases. *Id.* Litigation-related document productions can constitute exceptional circumstances and adds to the propriety of granting an *Open America* stay in this action. *See e.g.*, *Bower*, 2004 U.S. Dist. LEXIS 18369, at *5 (the FDA's "enormous litigation demands" contributed to findings of exceptional circumstances); *Edmonds v. Fed. Bureau of Investigation*, No. 02-1294, 2002 U.S. District LEXIS 26578, at *5 (D. D.C. Dec. 3, 2002)

(FOIA staff's time spent on administrative appeals, litigation and "large projects" contributed to finding of exceptional circumstances); *Ctr. for Pub. Integrity*, 2006 U.S. Dist. LEXIS 22281, at *6-7 ("the number of requests for records by courts or administrative tribunals" contributed to a finding of exceptional circumstance).

(ii) Requests from Congress.

The FDA has shown that document requests made by Congress have been another significant part of DIDP's workload. Sager Decl. ¶ 22. Although these requests are not made under FOIA and are not processed in FOIA's tracks, they are prioritized because they originate from Congress; and the same group of employees process them, resulting in fewer available resources for FOIA-specific processing. *Id.* During the past 12 months, including the pendency of Plaintiff's FOIA request, DIDP has reviewed approximately 44,000 pages of documents for Congress. *Id.* The large number of Congressional requests for CDER documents represents a significant increase in such requests beginning in 2004, and has resulted in a corresponding increase in the allocation of DIDP resources. *Id.*; *see, e.g.*, *Emerson v. CIA*, No. 99-0274, 1999 U.S. Dist. LEXIS 19511, at *3, n.2 (D. D.C. Dec. 15, 1999) ("unusual number of comprehensive Congressional requests" alleged and considered as exceptional circumstances).

(iii) Compliance with specific legislative enactments.

EFOIA and Executive Order 13,392,[5] requires DIDP to proactively review, redact, and post on the FDA's website certain drug approval packages, approval letters, and warning letters. Sager Decl. ¶ 23. DIDP makes available tens of thousands of pages of documents each year

[5]Federal agencies have been encouraged through various management directives, such as Executive Order 13,392, to increase the dissemination of records to the public without the need for FOIA requests.

regarding newly approved drugs, regardless of whether a FOIA request has been filed for such documents. *Id.* These proactive disclosure efforts reduce the number of incoming FOIA requests each year and so benefit the public, but consume the same level of staffing resources as if they had been made in response to FOIA requests. *Id.*

Further, only two weeks before DIDP received Plaintiff's FOIA request, President Bush signed into law the Food and Drug Administration Amendments Act of 2007 ("FDAAA"). FDAAA resulted in several new or increased obligations for DIDP: some took effect immediately and others must be implemented over the next six months. *Id.* ¶ 24. Six DIDP employees have been engaged specifically on projects related to FDAAA's new information disclosure requirements during some or all of the pendency of Plaintiff's FOIA request. *Id.*

Consequently, the FDA has shown that many of its resources are devoted to other important tasks.

e. Conclusion to exceptional circumstances analysis.

Based upon the evidence before it, the Court is convinced that the FDA has shown exceptional circumstances exist that are sufficient to support the grant of additional time to respond to Plaintiff's FOIA request. *See* 5 U.S.C. § 552(a)(6)(C)(i) (must show exceptional circumstances and due diligence for stay). The Court will now discuss the FDA's exercise of due diligence in responding to FOIA requests.

2. The FDA's Exercise of Due Diligence

Open America explained that the "due diligence" referred to in 5 U.S.C. § 552(a)(6)(C)(i) can be shown by processing the FOIA requests in a diligent manner. *Open America*, 547 F.2d at 616. That is, "good faith effort and due diligence of the agency to comply with [FOIA requests]

in as short a time as is possible by assigning all requests on a first-in, first-out basis, except those where exceptional need or urgency is shown, is compliance with [FOIA]." *Ctr. for Pub. Integrity*, 2006 U.S. Dist. LEXIS 22281, at *5 (citing *Open America*, 547 F.2d at 616). Cases subsequent to EFOIA have continued to hold that, where an agency is making good faith efforts and exercising due diligence in processing requests on a first-in, first-out basis, a stay of proceedings is authorized so long as the agency also demonstrates reasonable progress in reducing its backlog of pending requests. *See, e. g.*, *Appleton I*, 254 F. Supp.2d at 6, 9-10 & n. 4; *Wilderness Soc'y*, 2005 U.S. Dist. LEXIS 20042, at *21.

In the instant action, Plaintiff has not shown that there is exceptional need or urgency. Further, as explained *supra*, the FDA has submitted declarations showing that it has made reasonable progress in reducing its backlog of pending requests and Plaintiff has failed to rebut that showing. Consequently, the FDA's processing on a first-in, first-out two tract system support the finding that the FDA has exercised a good faith effort and due diligence to process the FOIA request in a timely manner.

B. Plaintiff's Request for Expedited FOIA Processing

In its memorandum opposing the FDA's request for a stay, Plaintiff argues for the first time that it is entitled to expedited FOIA processing. Plaintiff, however, has failed to exhaust its administrative remedies, which prevents this Court from reviewing Plaintiff's request. 5 U.S.C. § 552(a)(6)(E)(i). Plaintiff failed to seek expedited processing of its FOIA request from the FDA. FOIA directs agencies to promulgate regulations for expedited processing of requests when (1) "the person requesting the records demonstrates a compelling need" and (2) "in other cases determined by the agency." *Id.* FOIA requires that "demonstration of a compelling need

by a person making a request for expedited processing shall be made by a statement certified by such person to be true and correct to the best of such person's knowledge and belief." 5 U.S.C. § 552(a)(6)(E)(vi). Judicial review of an agency's refusal to provide expedited processing, or failure to respond in a timely manner, shall then be "based on the record before the agency at the time of the determination." 5 U.S.C. § 552(a)(6)(E)(iii).

The FDA's expedited processing regulations establish two main requirements: (1) the request for expedited processing must be filed in writing; and (2) the requestor must "include information that demonstrates a reasonable basis for concluding that a compelling need exists" and certify "that the information provided . . . is true and correct to the best of the requester's knowledge and belief." 21 C.F.R. § 20.44(d). A compelling need exists when the "failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual," or "[w]ith respect to a request made by a person primarily engaged in disseminating information, there is a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity." 21 C.F.R. § 20.44(a); 5 U.S.C. § 552(a)(6)(E)(v).

It is well understood that a FOIA requester must exhaust the available administrative remedies under FOIA before it may seek relief in the federal courts. *Oglesby v. United States Dep't of the Army*, 920 F.2d 57, 61-62 (D.C. Cir. 1990). Premature filing of a FOIA claim that has not matured because a party failed to exhaust mandatory administrative remedies prior to filing its complaint "is subject to dismissal for lack of subject matter jurisdiction." *Judicial Watch, Inc. v. U.S. Naval Observatory*, 160 F. Supp.2d 111, 112 (D. D.C. 2001). The rationale behind the exhaustion requirement is that it gives the agency "an opportunity to exercise its

discretion and expertise on the matter and to make a factual record to support its decision." *Oglesby*, 920 F.2d at 61 (citing *McKart v. United States*, 395 U.S. 185, 194 (1969)). Moreover, it allows agency supervisors an opportunity to correct mistaken denials of meritorious FOIA requests, thereby obviating the need for judicial review by the courts. *Id.*; *see also American Civil Liberties Union v. Dep't of Justice*, 321 F. Supp.2d 24, 28 (D. D.C. 2004) (noting judicial review of agency decisions concerning expedited processing requests "is appropriate at either of two moments: when the agency has denied a request for expedited processing, or when the agency has, upon administrative appeal, affirmed the denial of such a request").

In this action, Plaintiff did not request expedited processing of its FOIA request. *See* Sadler Decl., Ex. 1. Neither did Plaintiff offer and certify, as specified both by statute and regulation, information enabling the FDA to make a determination of "compelling need." *Id.* As a result, Plaintiff has failed to exhaust administrative remedies with respect to expedited processing.

Moreover, no record exists for the Court to review and, therefore, Plaintiff's claim is not "ripe." When ripeness is at issue, Sixth Circuit courts must, among other factors, "determin[e] . . . whether the factual record is sufficiently developed to produce a fair adjudication of the merits of the parties' respective claims." *Kentucky Press Ass'n v. Kentucky*, 454 F.3d 505, 509 (6th Cir. 2006). Because Plaintiff failed to seek expedited processing and created no factual record, there cannot be judicial review "based on the record before the agency at the time of the determination." 5 U.S.C. § 552(a)(6)(E)(iii).

Accordingly, the Court shall not attempt to review Plaintiff's belated request for expedited FOIA processing.

IV. CONCLUSION

Although the Court is persuaded that exceptional circumstances exist and that the FDA is exercising due diligence in processing Plaintiff's FOIA request, the Court is also aware that the request for a 20 month stay is the FDA's best estimate of the amount of time it will need before it is able to comply with Plaintiff's request. Further, the Court is aware of recent FOIA cases in which the courts granted a stay for a shorter amount of time than the government agency requested. *See e.g. Elec. Frontier Found.*, 517 F. Supp.2d at 120-21 (agency requested 27 months and was granted 12 months with the possibility of an extension); *Bower*, 2004 U.S. Dist. LEXIS 18369, at *8 ("I am uncomfortable in leaving the FDA quite so much to its own, unmonitored devices and leaving [the plaintiff] in a over two and one-half year vacuum going forward (on top of the nearly one full year that has expired since her filing of her FOIA request."). Hence, the Court is concerned that the FDA's estimate that it will take 20 months before it can respond to Plaintiff's FOIA request may be inflated so to account for the possibility that this Court may grant the stay for less time than requested.

On the other hand, the Court does not want to interfere with the FDA's processing its FOIA requests in an equitable manner, without prejudice to requesters waiting in line prior to Plaintiff. *See, e.g., Schweihs v. Fed. Bureau of Investigation*, 933 F.Supp. 719, 723 (N.D. Ill. 1996) (court declined to "vault" plaintiff's request over others in line); *see also, Open America*, 547 F.2d at 614 (Congress could not have "intended, by fixing a time limitation on agency action and according a right to bring suit . . . to grant an automatic preference by the mere action of filing a case.").

Consequently, the Court **CONDITIONALLY GRANTS** the Defendant's Motion for a

Stay. (Doc. # 10.) Specifically:

1. This case is **STAYED** until December 1, 2008 (ten months).

2. On December 1, 2008, the FDA shall file by affidavit, an accurate estimate of the amount of time remaining before it will be able to respond to Plaintiff's FOIA request.

3. Once the December 1, 2008 estimate is filed, the Court will order the stay continued in accordance with that more accurate estimate.

4. Defendant is placed on notice that the Court will not grant a stay that extends the period for compliance more than 15 months (May 18, 2009).

IT IS SO ORDERED.

/s/ Gregory L. Frost
GREGORY L. FROST
UNITED STATES DISTRICT JUDGE